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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,843

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Neil Graham

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EXAMINER

YOON, TAE H

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,843	Applicant(s) GRAHAM, NEIL	
	Examiner Tae H. Yoon	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-98 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41-98 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/25/05</u> . | 6) <input type="checkbox"/> Other: ____. |

Specification is objected since a subsection title, Brief Description of Drawing, is missing.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polymer obtained from reactants comprising polyethylene oxide, polyol (would be different from polyalcohol) and/or polyamine (would be different from polyfunctional amine) with a polyisocyanate and polyfunctional amine (would be different from polyamine) or polyalcohol (would be different from polyol), does not reasonably provide enablement for the recited reactants in the claimed language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The recited "polyol" encompasses "polyalcohol". The recited "polyamine" encompasses "polyfunctional amine". The specification does not give any definitions to aforesaid components. Furthermore, required particular reactants used are not defined in claims as reason given in the previous sentences, and thus, a nature of the claimed product is unclear. For example, required minimum reactants in claims 41 and 42 encompass polyamine (encompasses polyfunctional amine) and polyisocyanate, and a product from such reactants is not disclosed. Also, required minimum reactants in

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claims 80 and 81 encompass polyol and polyamine, and a product from such reactants is not disclosed either.

Claims 80-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The minimum required reactant in claims is one reactant or monomer such as polyol or polyamine, and said polyol or polyamine would not form a thermoplastic hydrogel which is in a non-macrogel state.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited “a thermoplastic hydrogel comprising ---- wherein the thermoplastic hydrogel is in a non-macrogel state” is confusing since said thermoplastic hydrogel would encompass macrogel and a hydrogel contains water. The instant paragraph [0001] teaches that the instant thermoplastic materials would swell in water to produce hydrogels and that said materials are defined as “thermoplastic hydrogels”. Thus, said

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“thermoplastic hydrogels” excludes water, but, a hydrogel contains water by default.

Also, said “thermoplastic hydrogels” which is swellable in water are in a macrogel state, not the recited “in a non-macrogel state”. Furthermore, complete polymerization of claim 90 (utilizing all of the recited six reactants in claim 80, for example) would yield a macrogel (crosslinked product).

The recited “polyol” encompasses “polyalcohol”, The recited “polyamine” encompasses “polyfunctional amine”. The specification does not give any definitions to aforesaid components. Furthermore, required particular reactants used are not defined in claims, and thus, a nature of the claimed product is unclear. For example, required minimum reactants in claims 41 and 42 encompass polyamine (encompasses polyfunctional amine) and polyisocyanate, and it is unclear whether a product from such reactants is claimed or not. Also, required minimum reactants in claims 80 and 81 encompass polyol and polyamine, and it is unclear whether a product from such reactants is claimed or not. Thus, claims are confusing and indefinite.

The recited “of” after “list” in claim 46 should be removed.

The recited “the ratios” in claim 49 and claim 87 and “the end product” in claim 74 lack antecedent basis, and thus they are indefinite.

Claims 55 and 57 recite addition of an amine or alcohol, and it is confusing whether said amine and alcohol encompass the recited amine and alcohol of claim 41 or not.

The recited “a final curing” in claim 59 is confusing since a nature of the final product is unclear and since claim 41 recites non-macrogel.

Claim 66 lacks antecedent basis in specification (see PP [0051] and [0052] which are not connected to each other) and broadens scope of claim 64 wherein an aliphatic amine is claimed. Also see PP [140].

The recited "excess OH groups" in claim 67 is confusing since it is unclear to which component or reactant said "excess OH groups" belongs.

The recited "under the specific conditions that are being used" in claim 70 is indefinite absent particular conditions. Also, a nature of the recited hydrogel after complete polymerization is unclear in claims 70 and 90. Is it a macrogel or non-macrogel? Furthermore, claim 41 encompasses a complete polymerization also, and a complete polymerization does not mean crosslinked gels (see example VIII of Braatz et al (US 5,039,458) wherein a complete polymerization with Mw of 17,000 is taught).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41-43, 49-51, 53, 54, 59, 69-75, 78-82, 87, 88, 91-93 and 96-98 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Braatz et al (US 5,039,458).

Braatz et al teach the instant prepolymer and a method of making in example VIII. A ratio of 2:1 for NCO and OH is taught at col. 5, lines 49-61. Polymerization of said prepolymer with water is taught at col. 7, lines 32-57 and in example X. Heating of hydrated polymers is taught at col. 17, lines 21-26, and said hydrated polymers would meet the instant completely polymerized product. Braatz et al teach employing hindered phenol and colorants at col. 9, lines 12-37 and in example VI (antioxidant, IRGANOX). Said colorants encompass dyes and pigments. A contact lens with a colorant would meet the instant cosmetic lens. Polymeric sheet or rod taught at col.9, lines 40-55 inherently would require pressing or extrusion, for example. Also, a mold for contact lenses is compression mold. Polymer cloud point study in example XIV would meet the instant claim 78 since the instant method reciting "comprising" permits additional step such as heating.

Thus, the invention lacks novelty.

Claims 41-43, 49-51, 53, 54, 59, 69-82, 87, 88 and 91-98 are rejected under 35 U.S.C. 103(a) as obvious over Braatz et al (US 5,039,458) in view of Ashton et al (US 2009/0010986 A).

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The invention further recites employing particular antioxidant over Braatz et al. However, use of the instant antioxidants in implants or body contacting polymeric hydrogel composition is well known in the art as taught by Ashton et al, PP [0224] wherein ascorbic acid and butylated hydroxyanisole (BHA) are taught. Said butylated hydroxyanisole would encompass the instant derivative and said BHA used in instant PP [0113].

It would have been obvious to one skilled in the art at the time of invention to further utilize ascorbic acid and butylated hydroxyanisole of Ashton et al in a contact lens of Braatz et al since Braatz et al teach utilization of an antioxidant and since the instant antioxidants are also well known in the art absent showing otherwise.

Claims 41-46, 49-57, 60, 62, 63, 67-73, 80-84, 87-91, 97 and 98 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Phelan et al (US 6,995,192).

Phelan et al teach a prepolymer prepared by reacting an isocyanate-capped polyurethane with an amine or monohydroxy compound or a mixture thereof and its use for a contact lens or ophthalmic device in abstract and example and at col. 2, line 24 to col. 3, line 17. Said ophthalmic device would encompass the instant lens of claim 98 absent further structural limitations. Said isocyanate-capped polyurethane is a reaction product of polyalkylene glycol, polyol with at least three hydroxyl groups and polyisocyanate. Polyethylene and polypropylene glycols are taught at col. 4, line 54. The instant amine and polyalcohol encompass those taught at cols. 7-10. The instant

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ratios of functional groups are taught at col. 11, lines 35-44. A method discussed at col. 12, lines 47-54 would meet the instant claims 54-57. Aqueous solution at col. 14, lines 22-27 or col. 23, lines 16-17 would meet the instant immersion in water. Various molding methods are taught at cols. 15 and 16. Irradiation inherently would yield heat meeting claim 71.

Thus, the invention lacks novelty.

Claims 41-46, 49-57, 60, 62, 63, 67-75, 79-84, 87-93 and 96-98 are rejected under 35 U.S.C. 103(a) as obvious over Phelan et al (US 6,995,192) alone, or in view of Baillet et al (US 2004/0018300 A) or Braatz et al (US 5,039,458).

The invention further recites employing antioxidant and a dye or pigment over Phelan et al. However, colored fashion contact lenses are well known in the art. Also, utilization of an antioxidant in polymeric compositions in order to prevent premature degradation is well known. Baillet et al teach employing stabilizers and a dye or pigment in ophthalmic articles in [0002]. Hydroxy group containing antioxidant (phenolic) is taught in [0055]. Braatz et al teach employing hindered phenol and colorant at col. 9, lines 12-37.

It would have been obvious to one skilled in the art at the time of invention to utilize an antioxidant or dye or pigment in a contact lens of Phelan et al with or without teaching of Baillet et al or Braatz et al since colored fashion contact lenses are well known in the art absent showing otherwise.

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Claims 41-46, 49-57, 60, 62, 63, 67-77, 79-84 and 87-98 are rejected under 35 U.S.C. 103(a) as obvious over Phelan et al (US 6,995,192) in view of Baillet et al (US 2004/0018300 A) or Braatz et al (US 5,039,458), and further in view of Ashton et al (US 2009/0010986 A).

The invention further recites employing particular antioxidant over Phelan et al, Baillet et al and Braatz et al. However, use of the instant antioxidants in implants or body contacting polymeric hydrogel composition is well known in the art as taught by Ashton et al, PP [0224] wherein ascorbic acid and butylated hydroxyanisole are taught. Said butylated hydroxyanisole would encompass the instant derivative and said BHA used in instant PP [0113].

It would have been obvious to one skilled in the art at the time of invention to further utilize ascorbic acid and butylated hydroxyanisole of Ashton et al in a contact lens of Phelan et al and Baillet et al or Braatz et al since utilization of an antioxidant in polymeric compositions in order to prevent premature degradation is well known in the art as taught by Baillet et al and Braatz et al and since the instant antioxidants are also well known in the art absent showing otherwise.

Claims 41-46, 49-57, 59, 60, 62, 63, 67-70, 72, 73, 80-84, 87-91, 97 and 98 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 02/00749.

WO teaches a contact lens made of a polymer obtained from a prepolymer comprising diol or triol, diisocyanate and polyalkylene oxide at pages 3 and 5 and in

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examples. NCO-terminated prepolymers are taught at pages 3 and 4. Other prepolymers of polyol, polyamine and polyisocyanate are also taught at pages 7-9. A curing of said prepolymer with water is taught at bottom of page 2 and top of page 5. Compression molding and injection molding are seen in line 7 of page 16, and said prepolymer is isocyanate terminated (page 9, line 4 and Formulas I and II). Said prepolymer is chain extended with polyols, polyamines or water (page 13, lines 12-14).

Thus, the invention lacks novelty.

Claims 41-46, 49-57, 59, 60, 62, 63, 67-70, 72, 73, 79-84, 87-91 and 96-98 are rejected under 35 U.S.C. 103(a) as obvious over WO 02/00749 alone, or in view of Baillet et al (US 2004/0018300 A) or Braatz et al (US 5,039,458).

The invention further recites employing antioxidant and a dye or pigment over WO. However, colored fashion contact lenses are well known in the art. Also, utilization of an antioxidant in polymeric compositions in order to prevent premature degradation is well known. Baillet et al teach employing stabilizers and a dye or pigment in ophthalmic articles in [0002]. Hydroxy group containing antioxidant (phenolic) is taught in [0055]. Braatz et al teach employing hindered phenol and colorant at col. 9, lines 12-37.

It would have been obvious to one skilled in the art at the time of invention to utilize an antioxidant or dye or pigment in a contact lens of WO with or without teaching of Baillet et al or Braatz et al since colored fashion contact lenses are well known in the art absent showing otherwise.

Claims 41-46, 49-57, 59, 60, 62, 63, 67-70, 72, 73, 79-84, 87-91 and 96-98 are rejected under 35 U.S.C. 103(a) as obvious over WO 02/00749 in view of Baillet et al (US 2004/0018300 A) or Braatz et al (US 5,039,458), and further in view of Ashton et al (US 2009/0010986 A).

The invention further recites employing particular antioxidant over WO, Baillet et al and Braatz et al. However, use of the instant antioxidants in implants or body contacting polymeric hydrogel composition is well known in the art as taught by Ashton et al, PP [0224] wherein ascorbic acid and butylated hydroxyanisole are taught. Said butylated hydroxyanisole would encompass the instant derivative and said BHA used in instant PP [0113].

It would have been obvious to one skilled in the art at the time of invention to further utilize ascorbic acid and butylated hydroxyanisole of Ashton et al in a contact lens of WO and Baillet et al or Braatz et al since utilization of an antioxidant in polymeric compositions in order to prevent premature degradation is well known in the art as taught by Baillet et al and Braatz et al and since the instant antioxidants are also well known in the art absent showing otherwise.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H. Yoon whose telephone number is (571) 272-1128. The examiner can normally be reached on Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tae H Yoon/
Primary Examiner
Art Unit 1796

THY/January 30, 2009